

MAR 4 2002

K020572
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Line Extension to the Accolade™ Hip System – Accolade™ TMZF® HA 132° Size 0 Hip Stem

Special 510(k) Premarket Notification

Special 510(k) Summary

Line Extension to the Accolade™ Hip System – Accolade™ TMZF® HA 132° Size 0 Hip Stem

Proprietary Name: Accolade™ TMZF® HA 132° Size 0 Hip Stem
Common Name: Artificial Hip Component
Classification Name and Reference: Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353

Proposed Regulatory Class: Class II
Device Product Code: 87 MEH

Predicate Proprietary Name: TMZF® Press Fit HA Stem
Predicate Regulatory Class: Class II
Predicate Product Code: 87 MEH

For Information contact: Nancy J. Rieder
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677
Phone: (201) 934-4364
Fax: (201) 760-8435

Description/Technological Comparison

The existing Accolade™ TMZF® HA Hip System features femoral stems in neutral, press-fit versions consisting of a variety of lengths and two neck angles, 132° and 127°. The subject Accolade™ TMZF® HA 132° Size 0 Hip Stem is an addition to the existing hip stems. It features a 132° neck angle and will be offered in an additional size (size 0). The Accolade™ TMZF® HA Size 0 Hip Stem is intended for smaller size patient populations. The subject hip stem, like the predicate hip stems, is manufactured using TMZF® alloy and is also coated with a

CP Titanium plasma spray coating and PureFix™ HA.

Intended Use

The subject hip stem is a single-use device intended for use in total hip replacement. It is intended for the reconstruction of the head and neck of the femoral joint. This hip stem is intended for primary reconstruction of the proximal femur or revision total hip arthroplasty. This device is intended for use with any currently available Howmedica Osteonics acetabular component and V40™ femoral heads that can be mated with a 5° 40' BG taper.

Indications:

- Cementless primary hip surgery in cases of non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, rheumatoid arthritis, and correction of functional deformity.
- Treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Revision procedures where other treatments or devices have failed.

Testing Summary

Testing was employed to evaluate the Accolade™ TMZF® Size 0 Hip Stem component. Analysis indicates that this hip stem component successfully maintains the proper strength requirements.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

Elizabeth A. Staub
Vice President
Quality Assurance, Regulatory Affairs and Clinical Research
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K020572

Trade/Device Name: Accolade TMZF HA 132° Size 0 Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or
non-porous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH
Dated: February 19, 2002
Received: February 21, 2002

Dear Ms. Staub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

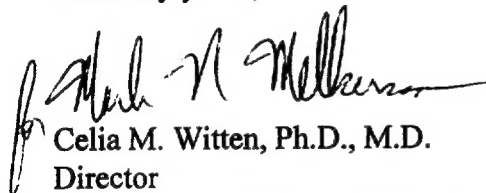
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Elizabeth Staub

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K020572Device Name: Line Extension to the Accolade™ Hip System – Accolade™ TMZF® 132° Size 0 Hip Stem

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)Prescription Use X OR Over-The-Counter Use _____ (Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark A. Miller
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020572